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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/734,150

12/15/2003

Frank E. Blondino

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21839 7590 04/25/2008  
BUCHANAN, INGERSOLL & ROONEY PC  
POST OFFICE BOX 1404  
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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT

PAPER NUMBER

1616

NOTIFICATION DATE

DELIVERY MODE

04/25/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/734,150	<b>Applicant(s)</b> BLONDINO ET AL.	
	<b>Examiner</b> MINA HAGHIGHATIAN	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15, 16, 19 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 15-16, 19, 23-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

### DETAILED ACTION

The indicated allowability of claims 15-16, 19 and 23-30 is **withdrawn** in view of the newly discovered reference(s) to Nichols et al (6,568,390) and to Cox et al (6,234,167). Rejections based on the newly cited reference(s) are as follow.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-16, 19 and 23-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-20 of U.S. Patent No. 6,568,390 in view of Rabinowitz et al (US20040202617). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims in view

of Rabinowitz et al (US20040202617). Here, both the instant claims and the reference claims are drawn to a method of generating an aerosol comprising supplying a liquid aerosol formulation to a flow passage and heating the liquid to form a vapor. The active agents suitable for the said method are "a thermally stable active agent". The difference between the two applications is that in the instant claims the active agent is buprenorphine, while the reference claims recite "a material". Rabinowitz teaches delivery of drugs through an inhalation route. Specifically, an aerosol containing active agents that are used in inhalation therapy is disclosed. Also a method of delivery is disclosed which method comprises heating a thin layer of an active agent, on a solid support, to form a vapor, and passing air through the heated vapor to produce aerosol particles having less than 5% degradation products. It is disclosed that typically, the aerosol particles have a mass median aerodynamic diameter (MMAD) of less than 5 microns. Preferably the particles have an MMAD of less than 3, less than 2 or less than 1 micron. Suitable active agents for the said aerosol vapor formulation include buprenorphine or its salts. The formulations may contain one or more excipients such as propylene glycol, glycerol, ethanol, methanol, etc.

Claims 15-16, 19 and 23-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-52 of U.S. Patent No. 6,234,167 in view of Rabinowitz et al (US20040202617). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims in view

of Rabinowitz et al (US20040202617). Here, both the instant claims and the reference claims are drawn to a method of generating an aerosol comprising supplying a liquid aerosol formulation to a flow passage and heating the liquid to form a vapor. The active agents suitable for the said method are "a thermally stable active agent". The difference between the two applications is that in the instant claims the active agent is buprenorphine, while the reference claims recite "a material". Rabinowitz teaches delivery of drugs through an inhalation route. Specifically, an aerosol containing active agents that are used in inhalation therapy is disclosed. Also a method of delivery is disclosed which method comprises heating a thin layer of an active agent, on a solid support, to form a vapor, and passing air through the heated vapor to produce aerosol particles having less than 5% degradation products. It is disclosed that typically, the aerosol particles have a mass median aerodynamic diameter (MMAD) of less than 5 microns. Preferably the particles have an MMAD of less than 3, less than 2 or less than 1 micron. Suitable active agents for the said aerosol vapor formulation include buprenorphine or its salts. The formulations may contain one or more excipients such as propylene glycol, glycerol, ethanol, methanol, etc.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINA HAGHIGHATIAN whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian  
Patent Examiner  
April 14,2008

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616